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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,022	10/23/2000	Steven Z. Wu	M-8873 US	3060

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,022

Applicant(s)

WU ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 20, 2002 has been entered.

Election/Restrictions

Claim 26 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8 because claim 26 was not elected by original presentation.

Information Disclosure Statement

The English language abstract of Japanese language document filed with the May 10, 2002 information disclosure statement is being treated as a concise explanation complying with 37 CFR 1.98(a)(3).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added language "string-like" is not defined and lacks original support. Therefore, not only is its scope not originally defined, but it also apparently expands the original meaning of the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-11 and 21-25, the phrase "string-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (WO 98/23228), or alternatively, under 35 USC 103(a) as

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being unpatentable over Brown et al (WO 98/23228) alone. Brown et al anticipates the claim language where the filament portions are the active agents in carriers (23,25) of Brown and they are "string-like" to the extent this claim language can be given patentable weight; see especially Figures 2 and 9 and pages 9 and 16. The active agent with carrier (23,25) is considered to be a fiber or "string-like" to the extent required by the present claim language.

Alternatively, one may not consider the active agent with carrier (23, 25) to be fibers or "string-like" as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make element(s) (23, 25) in a more solid or "string-like" nature because Applicants have not disclosed that therapeutic substance release device "string-like" provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well at releasing therapeutic substances because both the string-like material and the carrier(s) (23,25) have the common function of releasing therapeutic substances. Therefore, it would have been an obvious matter of design choice to modify Brown to obtain the invention as specified in the claims.

With regard to claim 6 specifically, it is noted that the limitation of exposing the body to a laser is a method limitation¹. For this reason, it is not afforded much patentable weight in that it is product-by-process limitation; see MPEP 2113, which is incorporated herein by reference there. In particular, if the product is not considered to

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be identical, it is considered to be at least substantially identical to the extent that is it clearly obvious thereover.

With regard to claim 8, it is noted that collagen, one of the agents of carriers, is a polymer of amino acids as are all proteins. For this reason, the claim language is fully met.

With regard to claim 11, the barrier as claimed is present by the top end of the groove, which converges into a slit. Therefore, the present claim is at least obvious in view of Brown et al, which clearly suggests it.

With regard to claim 22, Applicant is directed to see elements (114) of Figure 18.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (WO 98/23228) in view of Fischell et al (US 5,722,984). Brown et al at least obviates the claim language as set forth above and fails to teach the use of a radioactive isotope as claimed. Fischell et al, however, teaches that it was known to use radioactive isotopes in stent devices in order to reduce cell proliferation and restenosis; see the whole document, especially the abstract. Hence, it is the Examiner's position that it would have been obvious to use a radioactive isotope along with or in place of the active agents of Brown et al in order to reduce cell proliferation and restenosis as taught by Fischell et al.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (WO 98/23228) alone. Brown at least renders obvious the claim language as set forth in the Section 102 rejection above, but Brown fails to disclose the use of an adhesive with the filaments as claimed. However, since Brown discloses using other

elements therewith (see page 13) and since the use of adhesive provides no stated advantage or unexpected/unobvious result, it is the Examiner's position that it would have been prima facie obvious to use an adhesive with or on the drug depot of Brown in order to better secure it to the stent body.

Response to Arguments

Applicant's arguments filed December 20, 2002 have been fully considered but they are not persuasive.

With regard to new matter objection pertaining to the amended disclosure, the Examiner found that the explanation filed with the amendment was sufficient to show that the amended language had original support. For this reason, the objection has been withdrawn.

With regard to the 35 USC 112, first paragraph rejection traversal of the amendment, the Examiner maintains that "string-like" is not adequately originally described. The language to "resembles a string" (page 11, line 13 of the specification) does not adequately describe "string-like" because it is not disclosed as a definition thereof.

In response to the traversal of the 35 USC 112, second paragraph traversal, the Examiner asserts that "string-like" is synonymous with "string or the like." For this reason, the claim language is indefinite for the same reasons set forth in the rejection. In the Examiner's opinion, "string-like", given its broadest reasonable interpretation, is exemplary language that encompasses any non-disclosed elements that appear to be within its scope.

Applicants argue that Brown fails to disclose a filament having a string-like structure. However, the Examiner asserts that it does because "string-like" is vague and indefinite such that it fails to define over Brown. For this reason, the Examiner reasons that the claims are at least clearly obvious over Brown.

In response to the Applicants' argument that "string-like" must be given patentable weight, the Examiner posits that it has been given patentable weight, but it fails to define of Brown's carrier(s) (23,25). In fact, the reason that the Brown rejection was an alternative Section 102/Section 103 is due to the fact that "string-like" is given patentable weight.

In response to the Applicants' argument that there is no motivation to apply Brown under Section 103, the Examiner has modified the rejection as an obvious design choice rejection. This change has rendered the argument moot.

Conclusion

Applicants requested that they be contacted by telephone if the application is not in allowance. Instead, the Examiner decided to contact the Applicants via this Office action. Due to Applicants' request, this Office action has not been made final, even though it could have been, so that Applicants have an opportunity to amend the claims in response hereto.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

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applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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